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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,279	12/11/2001	Johnny Paul Speir	140-067a	2332
75	90 04/27/2006		EXAMINER	
Ward & Olivo			LIN, JERRY	
708 Third Ave New York, NY 10017			ART UNIT	PAPER NUMBER
ŕ			1631	
			DATE MAILED: 04/27/2000	5

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)		
Office Action Summary		10/014,279	SPEIR, JOHNNY PAUL		
		Examiner	Art Unit		
		Jerry Lin	1631		
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
<ol> <li>Responsive to communication(s) filed on <u>27 February 2006</u>.</li> <li>This action is FINAL. 2b) This action is non-final.</li> <li>Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11, 453 O.G. 213.</li> </ol>					
Dispositi	on of Claims				
5)	Claim(s) 30-33 is/are pending in the application 4a) Of the above claim(s) is/are withdraw Claim(s) is/are allowed.  Claim(s) 30-33 is/are rejected.  Claim(s) is/are objected to.  Claim(s) are subject to restriction and/or on Papers  The specification is objected to by the Examiner The drawing(s) filed on is/are: a) access Applicant may not request that any objection to the construction of the construction o	vn from consideration.  relection requirement.  r.  epted or b) □ objected to by the Edrawing(s) be held in abeyance. See on is required if the drawing(s) is obj	37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).		
Priority under 35 U.S.C. § 119  12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some colon None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.					
2) Notice (3) Inform	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other:			

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#### **DETAILED ACTION**

Applicants' arguments, filed February 27, 2006, have been fully considered and they are deemed to be persuasive in-part. Rejections not reiterated from previous office actions are hereby withdrawn. The following rejections are reiterated. They constitute the complete set presently being applied to the instant application.

## Status of the Claims

Claims 30-33 are under examination.

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 30-33 are rejected under 35 U.S.C. 102(e)(1) as being anticipated by Dasseux et al. (US 2002/0019023 A1, cited previously).

Regarding claim 30, Dasseux et al. disclose a method of analyzing a drug-dosed sample that includes ionizing a drug-dosed sample with metabolic products (page 12, paragraph 0117- page 13, paragraph 0127; page 10, paragraphs 0090-0091); introducing said ions to the analysis region of a mass spectrometer (page 13, paragraph 0132-page 14, paragraph 0136); continuously monitoring the ions and detecting

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changes to the sample (page 15, paragraph 0153); determining the molecular weight of each species present in a sample to determine the empirical formula and identifying each species by comparing the empirical formula to a database of formulas (page 17, paragraph 0169)

Regarding claim 31, Dasseux et al. teach updating databases with the changes that are detected (page 18, paragraph 0183; page 19, paragraphs 0186-0187).

Regarding claim 32, Dasseux et al. teach where the mass spectrometer is a FTMS (page 3, paragraph 0022).

Regarding claim 33, Dasseux et al. teach using electrospray ionization (page 13, paragraph 0125) as well as chemical ionization (page 12, paragraph 0118). Both of these methods are forms of Atmospheric Pressure Ionization.

## Response to Arguments

The applicants first respond to this rejection by stating that Dasseux et al. do not teach using molecular weight to determine the empirical formula of each species in a sample nor identifying each species. The Examiner disagrees.

Dasseux et al. state that they identify the mass spectra of extracts and that "know the exact mass of the peak, it could be easy to identify the molecule (either directly in the case of a small molecule or by elucidating the chemical formula . . . . "(page 17, paragraph 0169-0173). This statement teaches using the molecular weight to determine the empirical formula (i.e., chemical formula). In addition, Dasseux et al. teach identifying each species by searching a database (page 17, paragraph 0169).

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Applicants also state that Dasseux et al. teach away from the methods claimed in the present invention, because Dasseux et al. state that peaks are not identifiable until databases of HICS-FTMS peak profiles and the identities of the molecules corresponding to those individual peaks are complied. The Examiner disagrees.

Dasseux et al. are not suggesting that the peaks are unidentifiable, rather

Dasseux et al. are stating that the databases must be complied before the peaks can be identified. Once the databases are complied, Dasseux et al.'s method may be used to identify the peaks. Similarly in the last two steps of applicants' claim 30, if a database does not contain the empirical formula determined from the molecular weight, that species cannot be identified from that database. Dasseux et al. faces the same situation, however, it does not mean that the peaks are unidentifiable.

Furthermore, an argument that states that a reference teaches away from the claimed invention is not relevant to a rejection made under 35 U.S.C. §102, although it may be relevant a rejection made under 35 U.S.C. §103.

This rejection is maintained from the previous office action.

## Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

## **Contact Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 10:00am-6:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D. can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Representatives are available to answer your questions daily from 6 am to midnight (EST). When calling please have

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JL

MICHAEL BORIN, PH.D. PRIMARY EXAMINER

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